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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,538	09/24/2003	Michael Raschke	4951.220-US	4641

7590

03/24/2005

Reza Green, Esq.  
Novo Nordisk  
Pharmaceuticals, Inc.  
100 College Road West  
Princeton, NJ 08540

EXAMINER

GUPTA, ANISH

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

*ifl*

**Office Action Summary**

Application No.

10/669,538

Applicant(s)

RASCHKE ET AL.

Examiner

Anish Gupta

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9-24-03.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-3, 5-7 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chin and Giebel in view of Bak et al. (Bone) and Bak et al. (Clinical Orthopedics and Related Research).

The claims are drawn to methods of promoting and enhancing bone formations in those individuals with callus distraction using growth hormones.

The reference of Chin teaches that distraction osteogenesis is a technique utilizing natural healing process to generate new bone (see col. 1, lines 10-25). Giebel teaches that during callus distraction, or distraction osteogenesis, fibroblast networks that form collagen and connect the two ends of bone develop in the hematoma after coticotomy (see abstract). Giebel states that even

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during the lengthening process, the mineralization starts and intramembranous callus formation takes place during distraction osteogenesis (see abstract). The difference between the prior art and the instant application is that the prior art does not teach the use of Growth Hormone in the procedure of distraction osteogenesis.

However, Bak et al. (Clinical Orth.and Rel. Reas.) teach that the results obtained from an exogenous growth hormone injected in animals showed "a more abundant callus formation affecting a longer section of the bone" and GH "stimulated fracture healing in the present study as well, even though the injections were commenced after fracture" (see page 300). Bak et al. (Bone) teach that "administration of 2.0 mg of b-hGH per kg BW per day given in two injections produced a striking increase in the mechanical strength of healing and tibial fractures in the rat when evaluated by a three-point bending procedure after 40 days" (see page 237). In both reference animal models with dosages were conducted to demonstrate these conclusions. Therefore, there the art has clearly demonstrated that GH does promote bone formation by more abundant callus formation affecting a longer section of the bone and increase in the mechanical strength of healing and tibial fractures. Callus distraction or Distraction Osteogenesis is similar to a bone fracture except that the healing process is prolonged due to the constant distraction of the bone over a period of time. Note that the reference of Chin teach that distraction osteogenesis utilizes the natural healing process to generate new bone, a similar mechanism is involved in the healing of a regular bone fracture. Therefore, it would have been obvious to one of ordinary skill in the art to use GH to in distraction osteogenesis because GH promotes bone formation by more abundant callus formation affecting a longer section of the bone and increase in the mechanical strength of healing and tibial fractures.

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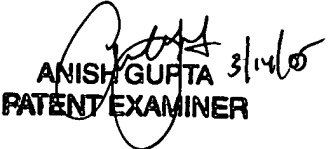
1. Claims 4, 8 and 12 rejected under 35 U.S.C. 103(a) as being unpatentable over Chin and Giebel in view of Bak et al. (Bone) and Bak et al. (Clinical Orthopedics and Related Research) as applied to claim 1-3, 5-7, 9-11 above, and further in view of Chen et al.

The claims are drawn to methods of promoting and enhancing bone formations in those individuals with callus distraction using growth hormones secretagogue.

Chin and Giebel in view of Bak et al. (Bone) and Bak et al. (Clinical Orthopedics and Related Research) have been discussed supra. The difference between the prior art and the instant application is that reference does not teach the use of growth hormone secretagogue.

However, Chen et al. teach growth hormone secretagogues are an inexpensive substitute to a growth hormone (see col. 1). The reference teaches a growth hormone secretagogue encompassed by the claims. Specifically, the reference teaches the compound of formula III (see claim 6). The reference further states the administration of the compounds of this invention for purposes of stimulating the release of an endogenous growth hormone can have the same effects or uses as growth hormone itself (see col. 35, lines 53-58). Therefore, these compounds would be effective in stimulating bone repair (see col. 35, line 61-62). Therefore, it would have been obvious to use growth hormone secretagogue instead of a growth hormone because one would expect the secretagogue to be effective bone repair in bone repair as the growth hormone and a growth hormone secretagogue is an inexpensive alternative to a growth hormone.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can normally be reached on (571) 272-0974. The fax phone number of this group is (571)-273-8300.

  
ANISH GUPTA 3/14/05  
PATENT EXAMINER